

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mylavarapu VENKATRAMESH *et al.*

Appln. No.: 10/647,517

Filed: January 16, 2004

For: Transgenic Plants Containing Altered
Levels of Sterol Compounds and
Tocopherols

Art Unit: 1621

Examiner: Deborah D. Carr

Confirmation No.: 5271

Atty. Docket: 16518.132

APPELLANTS' BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the Final Rejection of claims in the above-captioned patent application. A Notice of Appeal was filed on September 12, 2008. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

None.

3. Status of Claims

Claims 86, 89-94, and 97-110 are pending. Claims 1-70 were canceled and claims 71-90 were added in Appellants' Preliminary Amendment dated August 26, 2003. Claims 87-88 were canceled and claims 91-97 were added in Appellants' Response dated February 20, 2007.

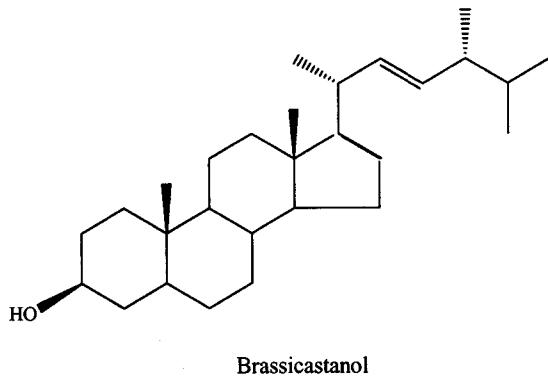
Claims 71-85 were withdrawn by the Examiner in the Office Action mailed May 14, 2007 as allegedly being directed to a non-elected invention. Claims 71-85, 95, and 96 were canceled without prejudice or disclaimer, and claims 98-110 were newly added by way of Appellants' Response dated September 14, 2007. Claims 89, 91-92, and 99-110 were withdrawn by the Examiner in the Final Office Action mailed March 14, 2008 as allegedly being directed to a non-elected invention. Claim 98 remains pending and has not been rejected or noted as allowed. As such, Applicants are treating claim 98 as allowable. Claims 86, 90, 93-94, and 97 stand finally rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. Claims 86, 90, 93-94, and 97 also stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fernholz *et al.* Appellants appeal all of the rejections of each of claims 86, 90, 93-94, and 97.

4. Status of Amendments

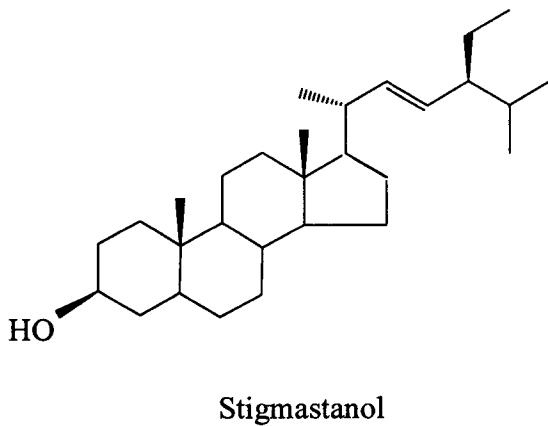
Appellants filed an Amendment on June 9, 2008 amending claims 86 and 90 without prejudice in response to the Final Office Action ("Final Action") mailed March 14, 2008. The new claims were indicated as entered by the Examiner in the Advisory Action mailed August 21, 2008 ("Advisory Action"). The Examiner indicated that the objection to claim 90 recited in the Final Action was withdrawn in view of Appellants Amendment filed on June 9, 2008. No further amendments were submitted following the Notice of Appeal filed on September 12, 2008.

5. Summary of Claimed Subject Matter

A. Independent Claim 86: The subject matter of independent claim 86 is directed to an oil comprising a compound selected from the group consisting of brassicastanol, at least one brassicastanol ester, stigmastanol, or at least one stigmastanol ester, and a mixture thereof, wherein said brassicastanol has the structure



and said stigmastanol has the structure



Specification at page 39, line 5 to page 40, line 6; and Examples 10-11 at page 115, line 5 to page 124, line 10.

(i) Dependant Claim 90. The subject matter of dependent Claim 90 is directed to the oil of claim 86, wherein said oil is in a transgenic seed having a reduced level of a compound selected from the group consisting of campesterol, a campesterol ester, campestanol, a campestanol ester, and mixtures thereof, compared to a second oil produced in a corresponding or non-transgenic seed. Specification at page 105, line 15 to page 107, line 11.

(ii) Dependant Claim 93. The subject matter of dependent Claim 93 is directed to the oil according to independent claim 86, further comprising a

compound selected from the group consisting of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, and a mixture thereof. *See, e.g.*, Specification at page 123, line 1 to page 128, line 6, and Table 7.

(iii) Dependant Claim 94. The subject matter of dependent Claim 94 is directed to the oil according to claim 93, further comprising a compound selected from the group consisting of a sitostanol, at least one sitostanol ester, and a mixture thereof, wherein said sitostanol, at least one sitostanol ester, or a mixture thereof comprises at least about 57% by weight of the total sterol compounds of said oil. Specification at page 100, lines 5-19; and at page 109, line 1 to page 110, line 2.

(iv) Dependant Claim 97. The subject matter of dependent Claim 97 is directed to the oil according to claim 86, further comprising a campesterol ester, campestanol, at least one campestanol ester, and a mixture thereof, wherein said campesterol ester, campestanol, at least one campestanol ester, and a mixture thereof, comprises about 5% to about 9% by weight of the total sterol compounds of the oil. Specification at page 115, line 5 to page 124, line 10, and Table 6.

6. **Grounds of Rejection to be Reviewed on Appeal**

The grounds of rejection to be reviewed in this Appeal are:

- (a) whether pending claims 86, 90, 93-94, and 97 are unpatentable under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter; and
- (b) whether pending claims 86, 90, 93-94, and 97 are unpatentable under 35 U.S.C. § 102(b) as allegedly being anticipated by Fernholz *et al.*

7. Argument

(a) Summary of Appellants' Position

The Examiner's assertion that claims 86, 90, 93-94, and 97 are directed to non-statutory subject matter under 35 U.S.C. § 101 is improper. The structure of the claimed stigmastanol, as described in the present specification, has not been found to occur in nature, and thus the claimed oil containing this compound is directed to statutory subject matter. As such, the rejection of claims 86, 90, 93-94, and 97 under 35 U.S.C. § 101 is improper and should be reversed.

Appellants also disagree with the Examiner's assertion that claims 86, 90, 93-94, and 97 are allegedly anticipated by Fernholz *et al.* under 35 U.S.C. § 102(b). The Examiner has not shown where Fernholz *et al.* describe a double bond at position C5 or C22 for either brassicastanol or stigmastanol as claimed. As such, the rejection of claims 86, 90, 93-94, and 97 under U.S.C. § 102(b) is improper and should be reversed.

(b) The Claimed Oils Are Not Directed to Non-Statutory Subject Matter Under 35 U.S.C. § 101.

In rejecting claims 86, 90, 93-94, and 97 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter, the Examiner asserts that “[w]hile brassicastanol [may] not be a naturally occurring phytostanol, stigmastanol which the claims read [on] is a commonly occurring plant stanol.” Final Action at page 4. Appellants respectfully disagree with the Examiner's assertion and submit that the Examiner's conclusion lacks a basis.

The burden is on the USPTO to set forth a *prima facie* case of unpatentability [under 35 U.S.C. § 101]...[t]herefore if USPTO personnel determine that it is more likely than not that the claimed subject matter falls outside all of the statutory categories, they must provide an explanation. MPEP § 2106(iv)(b). In alleging that the “stigmastanol which the claims read is a commonly occurring plant stanol”, the Examiner provides no explanation or evidence whatsoever that any “commonly occurring plant stanol” has the same structure as the structure of stigmastanol recited in claim 86. The specification states that “[s]till another aspect of the invention is the surprising discovery of the novel compound stigmastanol” and discloses the same structure as

recited in claim 86. *See* claim 86 and claims dependent thereon; and the specification at page 119, lines 4-16, page 127, lines 13-22. The specification further states that “[s]tigmastanol is a novel phytostanol produced in these transgenic plants...[t]he presence of stigmastanol in transgenic plants of the present invention is unexpected, and of unique commercial importance.” *Id.*

Appellants respectfully submit that the structure of the recited stigmastanol, as described in the present specification and claim 86, has not been found to occur in nature, and thus the claimed oil containing this compound is directed to statutory subject matter. Furthermore, the Examiner has not provided any explanation or evidence whatsoever for asserting that the recited stigmastanol occurs in nature. As such, Appellants respectfully submit that the Examiner’s assertions are improper and the rejection should be reversed.

(c) The Claimed Oils Are Not Anticipated Under 35 U.S.C. § 102(b) by Fernholz *et al.*

Claims 86, 90, 93-94, and 97 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Fernholz *et al.* In rejecting the claims, the Examiner erred in asserting that Fernholz *et al.* teaches an oil containing brassicasterol as one of its components which “reads on the instant oil, which only requires that one of the group consisting of brassicastanol, or its ester, stigmastanol, or its ester.” Final Action at page 4.

For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Fernholz *et al.* does not even come close.

Whatever else Fernholz *et al.* teach, they do not teach an oil comprising a compound selected from the group consisting of brassicastanol, at least one brassicastanol ester, stigmastanol, or at least one stigmastanol ester, and a mixture thereof with the structures disclosed in the present specification and recited in claim 86. *See* Specification at page 119, lines 4-16, and page 127, lines 13-22. As described in the specification, phytostanols such as brassicastanol and stigmastanol can be made commercially through hydrogenation of oils. However, the C-5 and C-22 double bonds in brassicastanol and stigmastanol made commercially

through hydrogenation are reduced. *Id.* In contrast, brassicasterol and stigmasterol are hydrogenated *by a plant* to brassicastanol and stigmastanol, respectively, in which both the C-5 and C-22 double bonds are *not* reduced. *Id.* The Examiner has not shown where Fernholz *et al.* describe a double bond at position C5 or C22 for either brassicastanol or stigmastanol as recited in the claims. Indeed, the brassicastanol and stigmastanol listed by Fernholz *et al.* are produced by hydrogenation outside of plants. *See* Fernholz *et al.* at page 143, first column. The Examiner has not provided any explanation or evidence to overcome the teaching in the specification that the compounds listed in Fernholz *et al.* are not the compounds recited in the claims.

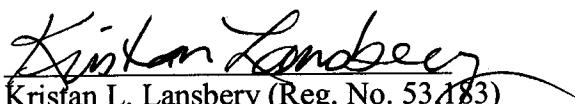
For the foregoing reasons, the teachings of Fernholz *et al.* do not anticipate brassicastanol, stigmastanol, or their esters as disclosed in the specification and recited in the claims, and the rejection of claims 86, 90, 93-94, and 97 under 35 U.S.C. § 102(b) is improper and should be reversed.

8. Conclusion

In view of the foregoing, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections and that the subject application be allowed.

Respectfully submitted

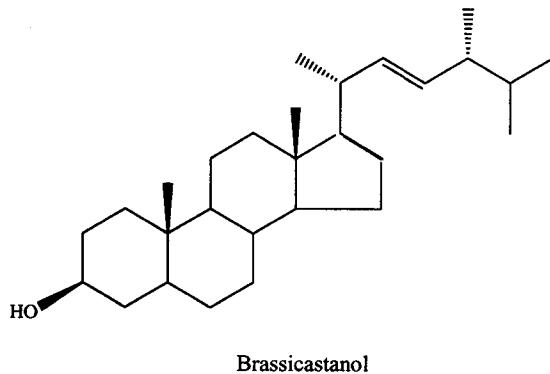
Date: November 12, 2008


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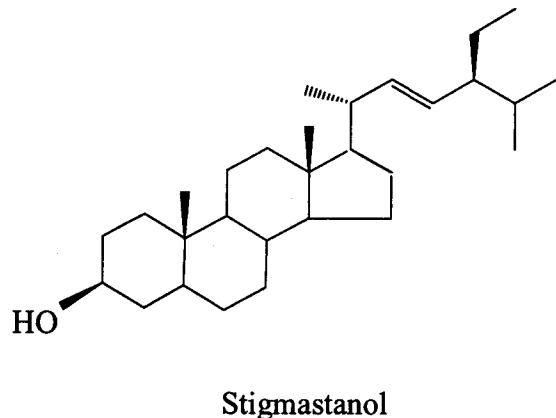
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CLAIMS APPENDIX

86. An oil comprising a compound selected from the group consisting of brassicastanol, at least one brassicastanol ester, stig mastanol, or at least one stig mastanol ester, and a mixture thereof, wherein said brassicastanol has the structure



and said stig mastanol has the structure



90. The oil of claim 86, wherein said oil is in a transgenic seed having a reduced level of a compound selected from the group consisting of campesterol, a campesterol ester, campestanol, a campestanol ester, and mixtures thereof, compared to a second oil produced in a corresponding or non-transgenic seed.

93. The oil according to claim 86, further comprising a compound selected from the group consisting of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, and a mixture thereof.

94. The oil according to claim 93, further comprising a compound selected from the group consisting of a sitostanol, at least one sitostanol ester, and a mixture thereof, wherein said sitostanol, at least one sitostanol ester, or a mixture thereof comprises at least about 57% by weight of the total sterol compounds of said oil.

97. The oil according to claim 86, further comprising a campesterol ester, campestanol, at least one campestanol ester, and a mixture thereof, wherein said campesterol ester, campestanol, at least one campestanol ester, and a mixture thereof, comprises about 5% to about 9% by weight of the total sterol compounds of the oil.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None